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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,040	02/01/2002	David Michael Goldstein	R0038H-CON	3728

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/07/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,040

Applicant(s)

GOLDSTEIN ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 22, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-32 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 22, 25, 26 and 28-30 is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-21, 23, 24, 27, 31, 32 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 19-32 and 39 are pending in the application.

Election/Restrictions

Newly submitted claim 39 (in-part) is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention which has been examined is where A and B are **simultaneously** an aryl or heteroaryl ring (e.g., A and B are both aryl or A and B are both heteroaryl). Newly added claim 39 claims that A and B **each independently** is an aryl or heteroaryl ring (e.g., A is aryl and B is heteroaryl; or A is heteroaryl and B is aryl; or A and B are both aryl; or A and B are both heteroaryl). Newly added claim 39 is of a much broader scope than the invention which has been examined and claim 39 embraces patentably distinct inventions which have not been examined in the instant application (e.g., A is aryl and B is heteroaryl; or A is heteroaryl and B is aryl).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claim 39 (in-part) is withdrawn from consideration as being directed to non-elected inventions (e.g., A is aryl and B is heteroaryl; or A is heteroaryl and B is aryl). See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 19-21, 23, 24, 27, 31, 32 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, under the definition of $R^3(r)$, an “or” is needed before “-OC(O)-NR'R” “. In claims 19-21, 24, 27 and 31, the R^6 variable lacks antecedent basis from the claims from which they depend. In claim 23, the first four (4) substituents lack antecedent basis from claim 22. In claim 39, under the definition of $R^3(f)$, “heteroalkyl” is misspelled. Claim 39 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other periods may be used elsewhere in the claims except for abbreviations {e.g., see the period before the definition of R^4 }.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 12 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faraci et al. {WO 94/13643}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim pyrazole products. Faraci et al. teach pyrazole products that are structurally similar to the instant claimed pyrazole products.

See in Faraci et al., for example, wherein A is $-C(=O)$, R_1 is amino, R_2 is alkyl, R_3 is phenyl substituted with a pyrrolyl group and R_4 is halophenyl (pages 1, 2 and 4). Also see, for example, the products on page 36, line 10; page 40, line 15; page 43, line 19; and page 44, lines 12-14.

Faraci et al. teach that the pyrazole products are useful in treating disorders such as inflammatory disorders, Alzheimer's disease and immune suppression (page 5, lines 1-12).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the products in the prior art and the instantly claimed products is that the instant claimed compounds are generically described in the prior art..

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious. The motivation to make the pyrazole products derives from the expectation that structurally similar products would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating inflammatory disorders. The instant claimed

invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed September 22, 2003 have been fully considered. Applicants argue the activity of the compounds of Faraci et al. and the compounds instantly claimed. Specifically, Applicants argue that Faraci et al. discloses corticotropin release factor (CRF) antagonists which are well known to be usable for treatment of stress related anxiety, depression and other CNS disorders. Applicants state that the instant invention is directed to compounds that inhibit p38MAP kinase for treatment of autoimmune conditions such as rheumatoid arthritis, bone resorption diseases and osteoarthritis, respiratory diseases and inflammatory conditions. Applicants also argue that the instant claimed compounds have unexpected results.

Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants claim pyrazole products. Faraci et al. teach pyrazole products that are structurally similar to the instant claimed pyrazole products. The difference between the products of Faraci et al. and the products instantly claimed is that some of the instant claimed products are generically embraced by the products of Faraci et al. Faraci et al. prepare specie which differ only at one position from the products instantly claimed or otherwise, the rejection of the claims would have been made under 35 USC § 102(b). Additionally, there is no requirement that the prior art must suggest that the claimed product will

have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990).

Although Applicants' are not claiming a method of use in the instant application, Faraci et al. teach that their compounds are useful in treating, for example, inflammatory diseases and Alzheimer's disease. On page 2 (lines 5-7) of the instant specification, Applicants disclose that, "Compounds that bind to p38 MAP are effective in inhibiting bone resorption, inflammation, and other immune and inflammation-based pathologies". On page 35 (lines 1-8) of the instant specification, Applicants also disclose that diseases such as various inflammatory diseases and Alzheimer's disease can be treated with the instant claimed compounds. A compound and its properties are inseparable. *In re Papesch*, 137 USPQ 43 (CCPA 1963). Therefore, one skilled in the art would administer the compounds of Faraci et al. to treat, for example, inflammatory diseases.

Further, Applicant relying upon comparative showing to rebut *prima facie* case must compare his claimed invention with the closest prior art. *In re Holladay*, 199 USPQ 516, 1978. For all the reasons given above, the instant claimed invention is found to have been obvious to one skilled in the art.

Allowable Subject Matter

Claims 16, 22, 25, 26 and 28-30 are allowed over the art of record.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

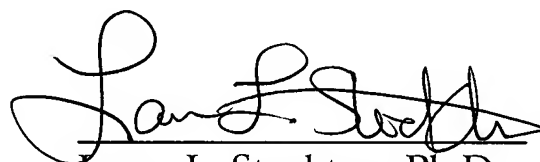
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains subject matter drawn to inventions nonelected. A complete reply to the final rejection must include cancellation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', with a stylized, sweeping flourish at the end.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

January 2, 2004